Remarks

Claims 55-103 are pending. New Claim 103 is added hereby, support for which is seen in the original specification at e.g., pages 4-5. The independent claims are Claims 55, 69, 77, 91 and 97.

The telephone conference of September 11, 2007, with Applicants' representative and Examiner is appreciated, during which the correctness of the §102 rejections was discussed, during which it was understood that Examiner would consider the matter further.

The Specification is amended at page 22 to correct a typographical error.

Information Disclosure Statement:

Page 2 of the Office Action indicated that certain items of non-patent literature previously cited would not be considered because Applicants did not submit copies of these references. Applicants, however, are not required to provide such copies, because these documents were cited in full compliance with 37 C.F.R. § 1.98(d), which provides that prior art made of record in a parent case does not need to be again submitted.

The earlier application was properly identified in the Fourth Supplemental I.D.S. of June 12, 2006, a further copy of which is appended to this response for the Examiner's convenience. As these items have already properly been made of record in an identified priority case, Applicants request that Examiner properly initial the previously submitted form listing these prior art references so as to clearly indicate these items have been made of record.

The Examiner apparently mistakenly referred to this Fourth Supplemental I.D.S. in the Office Action as having been filed "04/04/07." While there was an I.D.S. filed on that date, it cited only a single U.S. patent document for which no copy was required.

Double Patenting Rejections:

Claims 55-56, 64-65, 67 and 69 are rejected on the ground of obviousness-type double patenting over claims 1-5, 7-8 and 19-20 of U.S. Patent 5,797,898 (their docket MIT6962).

Claims 77-78, 81, 83, 85, 89-91 and 93-94 are rejected on the ground of obviousness-type double patenting over claims 1-2, 5-7, 10-12, and 15-16 of U.S. Patent 7,070,592 (their docket MIT8650 DIV).

Terminal Disclaimers with appropriate fee are provided hereby to obviate these grounds of rejection.

Rejections under §112:

Claim 77 is amended by deleting the objected-to feature. Thus the §112, ¶ 2 rejection is overcome. New claim 103 is added directed to this feature, which would be understood by one of ordinary skill in the art as indicating that the reservoirs are made by a microfabrication technique known in the art, such as those described in the specification at pages 4-5.

Claims 58 and 61 were rejected under §112, ¶ 1. Claim 61 is amended to recite the invention more precisely. The rejections are respectfully traversed.

Dependent Claim 58 recites that a reservoir section in the upper substrate portion is in communication with a reservoir section in the lower substrate portion, the two reservoir sections forming a single reservoir. This is illustrated in Figure 9C of the original specification, with reference to the accompanying text at page 33, lines 16-20, which recites "Top substrate portion 710a has reservoir 720a which is in communication with reservoir 720b in bottom substrate portion 710b." The specification uses nearly identical terminology as claim 58. Thus, there are an upper reservoir section (720a) and a lower reservoir section (720b), and these are in communication with one another.

Claim 61 depends from claim 60 and is amended to better recite that the two reservoir sections form a single reservoir upon the disintegration of the internal reservoir cap. Support for claim 61 and its base claim 60 is seen in Figure 9D of the original specification and its accompanying text at page 33, line 24 to page 34, line 9. It is commonly understood in the art to refer to a "section" as denoting a portion less than the entirety.

Thus is it believed claims 58 and 61 are supported in the disclosure.

Rejections on Prior Art:

Claims 77-102 are rejected under §102(b) as anticipated by U.S. Pat. 5,366,454 (Currie) (hereinafter "Currie"). That is, each of independent claims 77, 91 and 97 has been rejected under §102. The rejections are respectfully traversed.

Currie discloses an implantable drug dispensing device having compartments formed in a silicon wafer body 12 in which there is formed a drug-containing compartment 16. The compartment 16 is closed off by a silicon closure member 22 after the compartment is filled (or "charged") with the drug (see Fig 3, 4). Nowhere is it disclosed that closure member 22 ruptures or otherwise opens; it remains sealed. The drug delivery opening 20 is covered by a thin, rupturable silicon membrane 24 about 10 micron thick. Currie uses on his membrane the reverse piezo effect in the form of a piezoelectric thin film 34 that lays on top of silicon membrane 24 to rupture it, so that the membrane is always in a stressed condition, and when voltage is applied, the additional stress from the piezo stack ruptures the membrane 24, see column 2, lines 25-31 and column 5, line 59 to colum 6, line 28. Because Currie seeks to approximate with the rupturing membrane an ejection mechanism, see "Background" and column 1, lines 53-57, he even requires a bio-compatible film 50 to encapsulate his device, see Figure 4 and column 6 line 66 to column 7, line 3, in order to catch broken bits of membrane 24 from being ejected into the patient. In Currie's examples the "suitable piezoelectric materials which can be used in the present invention are lead zirconate titanate [commonly referred to as PZT], zinc oxide and cadmium sulphide", see column 2, lines 32-35. It is understood that these three disclosed materials are all crystalline, ceramic-type piezos.

Each of independent claims 77, 91 and 97 recites the feature that the reservoir caps are selectively disintegratable. Disintegrating the reservoir caps is not the same as rupturing them. The rupturing in Currie is purely mechanical, like throwing a rock through a window to shatter a thin, fragile membrane; indeed Currie requires a polymeric film 50 to trap the shards. In contrast, Applicants' claimed invention recites "disintegrating", and an example of disintegrating the reservoir caps is a phase change in the material, as shown by the examples in the original specification at page 22, lines 1-8, quoted here for convenience:

> "When an electric potential is applied between an anode and cathode, the conductive material of the anode above the reservoir oxidizes to form soluble compounds or ions that dissolve into solution, exposing the release system containing the molecules to be delivered to the surrounding fluids. Alternatively, the application of an electric potential can be used to create changes in local pH near the anode reservoir cap to allow normally insoluble ions or oxidation products to become soluble. This would allow the reservoir cap to dissolve and expose the release system to the surrounding fluids."

Applicants' original specification at page 4, top paragraph, also states the reservoir cap is formed of "materials that passively disintegrate, ... or materials that disintegrate upon application of an electric potential." (emphasis added). Since Currie fails to disclose Applicants claimed feature of disintegrating, the claims are not anticipated.

Furthermore, Claim 84 is not anticipated for the additional reason that Currie fails to disclose or suggest a biosensor; Currie discloses in the compartment 16 a medication that enters the body, see column 6, line 60-65.

Furthermore, Claims 85 and 94, which each recite that the reservoir caps comprise a metal film, are not anticipated for the additional reason that Currie discloses only a silicon membrane, and as the Examiner specifically conceded at page 5 of the Office Action "Currie does not disclose the reservoir cap formed of metal."

Claims 55-76, 85 and 94 are rejected under §103 over Currie, thus the independent claims 55 and 69 are rejected as obvious over Currie. The rejections are respectfully traversed.

Independent claim 55 recites that the reservoir cap is formed of metal. Independent Claim 69 recites that the reservoir cap is electrically conductive. Both claims 55 and 69 recite that the reservoir caps are disintegratable. While Examiner gave some analysis to the reasons for rejecting claim 55, with respect to claim 69 the Office Action (p.7) states simply "similar to rejection of claims 55-68 above", indicating Examiner's view that similar reasons applied.

It has already been discussed that Currie's thin (about 10 micron thick) silicon membrane 24 is brittle and mechanically breaks into pieces, thus it does not show or suggest Applicants' claimed feature of reservoir caps that are disintegratable.

It is noted that the silicon membrane is not metal, nor is it electrically conductive; silicon does not belong to the class of materials that are conductors (rather it is a semiconductor, e.g. when doped). More importantly, Currie relies on its inherent characteristic of being brittle or fragile so as to rupture when its pre-stress is elevated by the additional stress applied by the piezo stack, otherwise it would not function to release the drug. A metal or electrically conductive material is understood to be ductile, so one of ordinary skill in the art starting with Currie would not remove his thin, brittle silicon membrane and replace it with a metal reservoir cap or an electrically conductive cap.

Furthermore, it is respectfully pointed out that the rejections rest on faulty logic in the Office Action at page 5 (as can be best understood by Applicants), since Examiner appears to be arguing that (1) because in Currie the reservoir membrane 24 is formed of silicon, and that (2) the silicon membrane 24 is anodically bonded to the silicon body 12, thus allegedly (3) the silicon membrane can be used as an anode, and (4a) since Applicant discloses conductive metal caps serve as an anode, then he concludes thus it is obvious over Currie to have metal or electrically conductive reservoir caps. In what appears to be an alternate line of reasoning that purports to not rely the teaching of Applicants' disclosure in "step (4a)" above, Examiner appears to reason in the alternative that (4b) since allegedly silicon and metal can serve as anode material in electrochemical cells as evidenced by Auborn (U.S. Pat. 4,623,597) or Sapru (U.S. Pat 5,366,454), then he concludes that Currie thus suggests that metal or electrically conductive cap be substituted for the silicon membrane 24. This is incorrect factually and legally.

Firstly, the step of reasoning (indicated at 4a) that relies on Applicants' teaching is the absolute height of hindsight reasoning that is prohibited, since it uses Applicants' own disclosure as a blueprint against him. The rejection is legally insufficient for this reason. Applicants' disclosure is not part of the prior art. Nor can Applicants' disclosure be used, as Examiner has done here, as a motivation for fishing in the prior art for piecemeal elements from the wholly unrelated area of batteries simply because metal anodes are known in electrochemical cells.

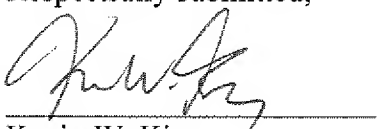
Secondly, Examiner makes an incorrect analogy. Currie does disclose that the silicon reservoir membrane 24 is anodically bonded to the silicon body 12, but it appears that Examiner does not understand what that term of art means. It is understood in the art of microfabrication that silicon is anodically bonded to silicon by using Pyrex glass, e.g. sodium rich Pyrex Corning #7740, as an intermediary, either in the form of a Pyrex thin film or Pyrex deposited (e.g. sputtered) on the surface of a silicon wafer. A large voltage (e.g. 1000 V) is then applied, with the negative cathode coupled to the Pyrex glass and the positive anode coupled to the silicon wafer. The voltage creates migration of Na+ ions in the glass towards the cathode which leaves a negative charge at the interface which, as the electrons from the Si are drawn to the anode, attracts the Si+ ions from the silicon wafer to form a strong SiO_2 interface to bond the silicon wafer to the glass. This allows the formation of SiO_2 at a thin interface layer to bond one silicon wafer to another silicon wafer by bonding each silicon wafer to opposite sides of the Pyrex interlayer. This is discussed in the standard treatise Fundamentals of Microfabrication: The Science of Miniaturization, Madou, M., 2d ed. At pp. 484-485 (CRC Press 2002). Thus, in the sense of the term of art in Currie, "anodically bonding" does not mean to use silicon as an anode. Examiner is reminded that Currie does not in the mechanism of rupturing his membrane rely on an electrical property of the silicon membrane but rather its mechanical property; that membrane is separated by insulation layer 30 from the electrically conductive films 32,36 that sandwich the piezo film 34 and energize the piezo film 34 in response to an applied signal.

The alternate reasoning attempting to draw an analogy to electrochemical cells is misplaced. Unfortunately Examiner has not pointed to where in Auborn or Sapru the alleged suggestion is to be found, and Applicants had to review those documents closely but without any guidance. Auborn discloses at column 3, lines 26-47 that an anode is preferably made of lithium metal, and that other oxidizable anode materials are "rare earth metals, ... or alloys thereof with other metallic elements, such as lithium alloys with aluminum ... or silicon", see col. 3, lines 40-47. This is not a suggestion of silicon being an anode, rather that silicon is alloyed with lithium in combination with rare earth metals. Sapru discloses that anodes should be formed by mixing a host matrix element with modifier elements on the atomic scale, see col. 9, lines 53-55. Sapru discloses for this mixture using a host element that can be from the list of "Zr, Nb., La, Si, Ca, Sc

and Y" with modifiers that can include "Cu, Mn, C, Fe, Ni, Al, Co, Mo, W, Li, and Re", see column 12, lines 15-29. Silicon appears to be mixed in or alloyed with other metals. Neither Auborn nor Sapru stands for the proposition that Examiner alleges that silicon be exchanged for a metal, or that the presence of silicon in an electrochemical system suggests using metal.

Allowance of each claim is respectfully solicited.

Respectfully submitted,



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TC/AU	:	3763
Examiner	:	C.L. Rodriguez
Docket No.	:	17648-0027
Customer No.	:	29052

FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The citation of information on the attached four pages of Form PTO-1449, "List of Art Cited by Applicants" is made pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98.

Inasmuch as this application relies on prior application Serial No. 09/665,303, filed September 19, 2000, for an earlier filing date under 35 U.S.C. § 120, no copy of any patent, publication or other information previously cited by or submitted to the Office in such prior application is being provided herewith.

The citation of this information does not constitute an admission of priority or that any cited item is available as a reference, or a waiver of any right the applicant may have under applicable statutes, Rules of Practice in patent cases, or otherwise.

No fee is believed to be required for consideration of this Supplemental Information Disclosure Statement. However, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 19-5029.

Respectfully submitted,

By: _____
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Date: June 12, 2006

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